

CLAIMS

1. Stabilising formulation for immunoglobulins G compositions, characterised in that the formulation includes a sugar alcohol, glycine, and a non-ionic detergent, in order to be suitable for the stabilisation of immunoglobulins G compositions in liquid form and in lyophilised form.
2. Formulation according to claim 1, consisting of the said sugar alcohol, glycine and non-ionic detergent.
3. Formulation according to any one of claims 1 and 2, characterized in that the sugar alcohol is mannitol.
4. Formulation according to claim 3, characterized in that the concentration of mannitol is between 30 g/l and 50 g/l.
5. Formulation according to any one of claims 1 and 4, characterized in that the concentration of glycine is between 7 g/l and 10 g/l.
6. Formulation according to any one of claims 1 and 5, characterized in that the concentration of the non-ionic detergent is between 20 and 50 ppm.
7. Immunoglobulins G composition in liquid form, comprising the stabilising formulation according to any one of claims 1 to 6.
8. Immunoglobulins G composition in lyophilised form, comprising the stabilising formulation according to any one of claims 1 to 6.
9. Immunoglobulins G composition according to claim 8, characterized in that it includes an amount of polymers less than 0.3 % after
10. Immunoglobulins G composition according to claim 8, characterized in that it includes an amount of polymers less than 0.3 % after

a 12 months storage period at room temperature or for 6 months at 40°C.

11. Immunoglobulins G composition according to any one of claims 7 to 10, characterized in that it includes an amount of dimers less than 7 % after a 24 months storage period at 4°C.

12. Use of a stabilising formulation according to any one of claims 1 to 6, for stabilisation of immunoglobulins G compositions in liquid form obtained directly by fractioning of human plasma.

13. Use of a stabilising formulation according to any one of claims 1 to 6, for stabilisation of immunoglobulins G compositions in lyophilised form.

14. Use of a stabilising formulation according to any one of claims 1 to 6, for stabilisation of immunoglobulins G compositions in liquid form obtained after reconstitution in a suitable aqueous medium of immunoglobulins G compositions in lyophilised form.

25

30

35